ANDA 76-030

August 20, 2001

Geneva Pharmaceuticals Technology Corporation
Attention: Mahendra Patel, Ph.D.
2400 Route 130 North
Dayton, New Jersey 08810

Dear Sir:

This is in reference to your abbreviated new drug application dated November 15, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Flecainide Acetate Tablets USP, 50 mg, 100 mg and 150 mg.

Reference is also made to your amendment dated May 24, 2001, June 4, 2001 and July 26, 2001.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention.

The listed drug product (RLD) referenced in your application, Tambocor™ Tablets of 3M Pharmaceuticals, Inc., is subject to a period of patent protection which expires on February 10, 2004, [U.S. Patent No. 4,642,384, (the '384 patent)]. Your application contains a Paragraph IV Certification to the '384 patent under Section 505(j)(2)(A)(vii)(IV) of the Act. This certification states that the '384 patent is invalid, unenforceable or will not be infringed by your manufacture, use, or sale of the drug product. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug application shall be made effective immediately, unless an action is brought against Geneva Pharmaceuticals Technology Corporation (Geneva) for infringement of the patent that is the

subject of the certification (the ‘384 patent). You have notified the agency that Geneva has complied with the requirements of Section 505(j)(2)(B) of the Act and that no legal action regarding the '384 patent was brought against Geneva Pharmaceutical Technology Corporation within the statutory forty-five day period.

Furthermore, please note that ANDA 75-442 submitted by Alphapharm PTY. LTD. for this drug product and containing a Paragraph IV Certification was accepted for filing by this office prior to the filing of your application. This application was approved on July 31, 2001. Consequently, Alphapharm is deemed eligible for 180-days of generic drug market exclusivity as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. Such exclusivity will begin to run either from the date Alphapharm begins commercial marketing of the drug product, or in the absence of marketing, from the date of a decision of a court finding the patent invalid or not infringed, whichever event occurs earlier. We believe that your application for this drug product will be eligible for final approval beginning one hundred and eighty (180) days following one of these precipitating events. We refer you to the agency’s guidance documents entitled “180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments” (June 1998) and “Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act” (March 2000) concerning the court decision trigger. Therefore, final approval cannot be granted until Alphapharm’s 180-day generic drug exclusivity has expired.

Because the Agency is granting a tentative approval for this application, please submit a MINOR AMENDMENT – FINAL APPROVAL REQUESTED approximately 90 days prior to when you believe your application may be considered for final approval. Your amendment must provide:

1. updated information related to labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or

2. a statement that no such changes have been made to the application since the date of tentative approval.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The amendment should be designated as a MINOR AMENDMENT in your cover letter. Before you submit the amendment, please contact Bonnie McNeal, Project Manager, at 301-827-5849, for further instructions.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

TENTATIVE APPROVAL